

**REMARKS**

Claims 53-68 and 78-79 have been canceled for prosecution at a later date. New claims 80-93 have been added. Applicants submit that no new matter has been added by this action. Support for new claim 80 can be found in the specification at, *inter alia*, page 14, lines 1-26 and at page 18, lines 3-13. Support for new claim 81 can be found in the specification at, *inter alia*, page 18, lines 3-13. Support for new claims 82-93 (claims 54, 56-68, and 78-79 as originally filed) can be found in the application at, *inter alia*, page 12, lines 9-14, page 14, lines 1-6 and lines 26-29, page 18, lines 3-13 and lines 24-25, page 41, lines 21-28.

Therefore, upon entry of this amendment, claims 80-93 will be pending in the application.

The outstanding rejections are addressed individually below.

**I. Priority**

According to the Office Action, the pending application (U.S. Application No. 10/042,644) cannot claim priority to the provisional application (U.S. Application No. 60/260,541) because the provisional application allegedly does not provide support for the pending application. Applicants respectfully traverse this priority determination.

A later filed application must be an application for a patent for an invention that is also disclosed in the prior application (see MPEP § 201.11). In addition, the disclosure of the invention in the prior application and the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. *See Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551 (Fed. Cir. 1994).

Applicants aver that the disclosure in the provisional application contains ample and sufficient support for the amended claims. In particular, such support can be found in the provisional application for claims 80, 86-88, and 94 on page 4, lines 9-10 and lines 15-22; on page 5, lines 1-7; in Example 4 (page 15, lines 3-11; and in Example 7 (page 15, lines 21-25). Support for claims 81-84, and 92-93 can be found on page 4, lines 2-4; and on page 9, lines 2-4. Furthermore, support for claim 91 can be found in Example 1 (page 10, line 15 to page 12, line

19); in Example 3 (page 13, lines 5-24); and in Example 8 (page 16, lines 5-22). Accordingly, Applicants assert that the instantly claimed invention is supported by the provisional application (U.S. Application No. 60/260,541).

Therefore, Applicants respectfully request that the Examiner reconsider this priority determination, and allow priority for the instantly claimed invention to be January 9, 2001.

**2. *Claim Rejections under 35 U.S.C. § 102(b)***

Claims 53-68 and 78-79 were rejected as being anticipated by Benoit *et al.*, U.S. Patent No. 5,919,453. The Office Action states that the Benoit reference teaches the use of antibodies against interferon type I as an antagonist of the biological activities of IFN  $\alpha$  (see Office Action, pg. 4). It is further alleged that the Benoit reference teaches using antibodies to inhibit or neutralize IFN  $\alpha$  (see Office Action, pg. 4). Applicants respectfully traverse this rejection for this reasons that follow.

For a claim to be anticipated under § 102(b), the anticipating reference must teach each and every element of the claim, either expressly or inherently (see MPEP § 2131).

In order to facilitate prosecution, but not in acquiescence to this rejection, Applicants have added new claims 80 and 81 and canceled claims 53-69, and 78-79. Applicants respectfully aver that the Benoit reference does not anticipate these newly added claims because it does not teach a type I antagonist antibody that falls within the scope of new claim 80. For example, Applicants note that the Benoit reference does not teach the use of antibodies directed against IFN $\alpha$ . Instead, the Benoit reference teaches the use of monoclonal antibodies against the IFN $\alpha$  receptor (see column 2, lines 61-67, column 3, lines 34-59, and column 4, lines 1-20). Furthermore, Examples 1-4 of Benoit teach the development and use of monoclonal antibodies against the IFN $\alpha$  receptor. The Benoit reference is, therefore, drawn to compositions and methods of treatment utilizing monoclonal antibodies against the IFN $\alpha$  receptor. Thus, the amended claims are not within the scope of the Benoit reference.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

In addition, claims 53-68 and 78-79 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Skurkovich *et al.*, U.S. Patent No. 5,888,511. The Office Action states that Skurkovich *et al.* teaches the use of antibodies against (i) IFN  $\alpha$ , (ii) IFN  $\gamma$ , and (iii) IFN  $\alpha$  receptor to treat autoimmune diseases such as SLE, rheumatoid arthritis, and diabetes type I (see 8/23/2005 Office Action, pg. 5). Applicants respectfully traverse this rejection for the reasons that follow.

According to MPEP § 2121.01, a reference must contain an “enabling disclosure” to qualify as § 102(b) prior art. If the invention cannot be produced without undue experimentation, mere naming or description of the subject matter is insufficient (see MPEP, § 2121.01). Therefore, a disclosure that does not enable one of skill in the art to produce the invention without undue experimentation would not be applicable as prior art against a pending application (see MPEP, § 2121.01).

Applicants respectfully assert that the Skurkovich reference does not enable the singular use of anti-IFN  $\alpha$  antibodies as a treatment for autoimmune diseases such as SLE or psoriasis. Rather, the Skurkovich reference provides for treatments using a pharmaceutical composition in which *a plurality of two or more components* is used as a treatment for an autoimmune disease (see Examples 4-6, and column 4, lines 38-67, column 5, lines 1-52). In particular, the specification of the Skurkovich reference does not enable the singular use of an anti-IFN  $\alpha$  antibody as a treatment of autoimmune diseases.

Furthermore, Applicants disagree that the Skurkovich reference enables a method of treatment using an anti-IFN  $\alpha$  antibody to treat AIDS (see Example 7). Specifically, Example 7 provides for the treatment of AIDS described in Skurkovich *et al.* (*Med. Hypoth.* (1994) 42:27-35) wherein an aberrant, abnormal, and pH labile form of IFN (“abIFN”) is neutralized with an antibody. Accordingly, Skurkovich *et al.* does not teach the neutralization of normal IFN with the antibodies, in general, or that the neutralization of normal IFN could treat AIDS in particular. Neither does this reference provide for the use of anti-abIFN antibodies to neutralize normal IFN $\alpha$ . Therefore, the reference merely provides for the neutralization of abIFN, but not normal IFN $\alpha$ .

Additionally, the Skurkovich reference does not establish that anti-IFN $\alpha$  antibodies can be used alone for the treatment of diseases other than rheumatoid arthritis. To the contrary, Examples 4-6 disclose the use of anti-IFN $\gamma$  antibodies, anti-IFN $\alpha$  antibodies, or other autoimmune inhibitors, *in combination* (see Examples 4-6). The Skurkovich reference shows that IFN  $\alpha$  therapies are effective against rheumatoid arthritis, while disclosing combination therapies for other diseases (e.g., SLE). One of skill in the art would interpret the Examples and the detailed discussion of combined therapies in the Skurkovich reference as impliedly disclosing only *combination therapies* for autoimmune diseases such as SLE, MS, and juvenile rheumatoid arthritis. Therefore, Applicants respectfully assert that the Skurkovich reference does not teach the use of anti-IFN $\alpha$  antibodies directed against normal IFN $\alpha$  as therapies for AIDS or other conditions such as SLE.

Accordingly, Applicants respectfully request that the §102(b) rejection be reconsidered as above, and withdrawn.

### **CONCLUSIONS**

In view of the claim amendments set forth above, Applicants respectfully request rejections contained in the Office Action mailed on August 23, 2005 be reconsidered and withdrawn. Applicants also submit that the pending claims are in condition for allowance.

The time for responding to this action has been extended to February 23, 2006 by the accompanying Petition for a Three Month Extension of Time and payment of fee. Applicants believe no other fees are due in connection with this Amendment. However, if there are any fees due, please charge them to Deposit Account 08-0219. Also, please credit any overpayment to the same Deposit Account.

Application No. 10/042,644  
Amtd. Dated February 23, 2006  
Reply to Office Action of August 23, 2005

If the Examiner believes that any further discussion of this communication would be helpful, please contact the undersigned at the telephone number provided below.

Respectfully submitted,

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